

REMARKS

I. Information Disclosure Statement

The Examiner noted that the references cited in the application have not been considered because an Information Disclosure Statement form has not been submitted to the Office. (Office Action at 2.) Applicants have filed with this response an Information Disclosure Statement under 37 C.F.R. § 1.97(c), a separate paper listing all relevant patents and publications listed in the Specification, copies of the relevant foreign patents and publications, and the appropriate fees. Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

II. Amendments

Prior to this amendment, Claims 1-35 were pending. Claims 1, 4-15, and 23-35 were withdrawn from consideration. In the last Office Action, the Examiner rejected Claims 2, 3, and 16-22. By this amendment, Applicants cancel Claims 17, 20, and 21; amend Claims 2, 3, 16, 18, 19, and 22; and add new Claims 36-53. The new claims and amendments to the existing claims do not add new matter. Claims 1-16, 18-19, and 22-53 are now pending. Claims 2, 3, 16, 18, 19, 22, and 36-53 are under examination.

The Examiner pointed out that Figure 3 refers to sequences without also referring to their sequence identifiers. (*Id.* at 3.) Applicants have amended the Specification to replace the brief description of Figure 3, appearing on page 16, lines 6-10 of the Translation of the Specification as originally filed, with a new paragraph, which includes sequence identifiers. Further, the Examiner noted that trademarks, TRIZOL™ and

RNA^{sin}™, listed on page 19 of the Specification should be capitalized. Applicants have amended the Specification to replace the paragraph appearing on page 19, lines 15-21, with a new paragraph, which includes each trademark in capital letters followed by the generic term for the product.

III. Objections to Claims

The Examiner objected to Claim 17 as being of improper dependent form for failing to further limit the subject matter of a previous claim. (*Id.* at 2.) Applicants have canceled Claim 17, thereby obviating the Examiner's objection. Further, the Examiner objected to Claims 3 and 16-22 as being dependent upon non-elected claims and Claims 16-22 as being in improper form. (*Id.* at 3-4.) Applicants have canceled Claims 17, 20, and 21; have amended Claims 3, 16, 18, 19, and 22 so they no longer depend from non-elected claims and are no longer multiple dependent; and have added new Claims 36-53, which are derived from previous Claims 3, 16, 18, 19, and 22 and do not depend from non-elected claims. Further support for new Claim 43 can be found in the Translation of the Specification as originally filed at page 5, line 25 through page 6, line 1. The amendments to existing claims and the newly added claims do not add new matter. Applicants submit that the foregoing amendments obviate the Examiner's objection to Claims 3 and 16-22.

Applicants also amended the following claims in the manner specified:

- 1) amended Claims 3, 16, and 22 so that the term, "*Leishmania*," is italicized;
- 2) amended Claim 3 from "protein...characterized in that it is" to "protein...which is" and "protein...with sequence SEQ ID No: 2" to "protein...having sequence SEQ ID NO: 2;"
- and 3) amended Claim 16 from "said immunogenic composition being capable of" to

“said immunogenic composition is capable of.” These amendments do not add new matter.

IV. Written Description Rejection under 35 U.S.C. § 112, ¶1

The Examiner rejected Claims 2-3 and 16-22 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that “Claims 2-3 drawn to the protein fails [sic] to recite any associated function.” (*Id.* at 7.) Applicants have amended Claim 2 to recite, “wherein said protein is predominantly expressed in the most virulent isolates of the parasite.” Support for this amendment can be found in the Translation of the Specification as originally filed at page 1, lines 5-6; page 17, lines 11-16; page 26, line 23 through page 27, line 4 and in Figure 7.

In reference to Claim 3, the Examiner stated that the written description “only sets forth specific sequences identified by their SEQ ID Numbers, therefore the written description is not commensurate in scope with the claims drawn to any functional variant.” (*Id.* at p. 6-7.) The Examiner further stated that neither the specification nor the claims teach how to define or how to obtain functional variants. Though not agreeing with the grounds for this rejection, Applicants have amended Claim 3 to exclude language relating to functional variants of LmPDI.

However, Applicants present new Claims 43-53, in which the protein is a functional variant of a *Leishmania major* protein disulfide isomerase (LmPDI) protein of *Leishmania major*, wherein the variant has at least 80% identity with SEQ ID NO: 2 and is capable of complementing LmPDI in an infectivity test carried out with an *L. major* strain in which the LmPDI gene has been deactivated. The variants are defined within

the claim by their ability to complement LmPDI in an *L. major* strain with a deactivated LmPDI gene. Further, the specification teaches examples of different species of *Leishmania*, namely, *L. infantum* MC, *L. infantum* Visc, and *L. donovani*, that possess an LmPDI gene that appears to be conserved. (Figure 5B, page 16, line 25 through page 17, line 3, and page 26, lines 7-9.) It follows that the proteins expressed by these genes from other species are functional variants of a *Leishmania major* protein disulfide isomerase (LmPDI) protein of *Leishmania major*. Applicants submit that Claims 2 and 3 as amended and new Claims 43-53 comply with the written description requirement.

Claims 16-22 were rejected by the Examiner as lacking written description of an immunogenic or vaccinating composition comprising four amino acids, which would be capable of *in vitro* stimulation of the proliferation of mononuclear cells originating from individuals who have come into contact with *Leishmania major* or capable of inducing an immune response of the Th1 type when administered to a human or animal host or that is intended to protect a human or animal host against leishmaniasis. (*Id.* at 9.) While Applicants do not agree with the grounds of this rejection, Applicants have amended Claim 16 to recite, "wherein said protein is a polypeptide of at least 10 amino acids." This amendment is supported by the Translation of the Specification as originally filed at p. 6, line 23 through p. 7, line 1. Further, new claims 39-45 and 47-53, which are based on original claims 16, 19, and 22, also are limited by the protein being a polypeptide of at least 10 amino acids.

The Examiner stated that "[t]he term 'vaccinating' encompasses the ability of the specific antigen to induce protective immunity to a bacterial infection or disease induction." (*Id.* at p. 9.) Applicants have cancelled Claims 20 and 21, which recited the

term “vaccinating” and amended Claim 22 to no longer recite the term “vaccinating,” thereby obviating the Examiner’s rejection.

In view of the amendments to Claims 2, 3, 16, 18, 19, and 22 and the cancellation of Claims 17, 20, and 21, Applicants respectfully request that the rejection of Claims 2, 3, 16, 18, 19, and 22 under 35 U.S.C. § 112, first paragraph be withdrawn.

V. Enablement Rejection under 35 U.S.C. § 112, ¶1

The Examiner rejected Claims 2-3 and 16-22 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. With regard to Claim 3, the Examiner stated that “the recitation of similar sequence identity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecules and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement.” (*Id.* at p. 12.) As stated above, Applicants have amended Claim 3. With regard to Claim 16, the Examiner stated that a protein requiring only four amino acids is not enough to create an epitope. As previously presented, the amendment to Claim 16 to include the language, “wherein said protein is a polypeptide of at least 10 amino acids,” obviates the Examiner’s rejection. In view of the amendments to Claims 2, 3, 16, 18, 19, and 22 and the cancellation of Claims 17, 20, and 21, Applicants respectfully request that the rejection of Claims 2, 3, 16, 18, 19, and 22 under 35 U.S.C. § 112, first paragraph be withdrawn.

VI. Rejection under 35 U.S.C. § 112, ¶2

The Examiner rejected Claims 2-3 and 16-22 under 35 U.S.C. § 112, second paragraph, as being indefinite because there is insufficient antecedent basis for the limitations, “the potential active site,” “the protein disulfide-isomerase,” and “the LmPDI

protein of *Leishmania major*,” which are recited in Claims 2 and 3. (*Id.* at 15.) The Examiner also rejected Claim 3 because “acronyms like LmPDI must be spelled out when used for the first time in a chain of claims.” (*Id.*) Applicants have amended Claims 2 and 3 to recite, “a *Leishmania* parasite,” “a potential active site,” “a protein disulfide-isomerase,” and “a *Leishmania major* protein disulfide isomerase (LmPDI) protein.” Further, the Examiner rejected Claim 3 as being indefinite because it recites a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation. (*Id.* at p. 16.) Applicants have amended Claim 3 to no longer reflect the language that the Examiner finds indefinite. Applicants respectfully request that these rejections of Claims 2-3 and 16-22 under 35 U.S.C. § 112, second paragraph be withdrawn.

Further, the Examiner rejected claims 3, 17-19, and 21-22 because “a or an” should be changed to “the” when referring to “a protein,” “an immunogenic composition,” or “a vaccinating composition.” (*Id.*) Applicants respectfully traverse this rejection because Claim 2, as amended, states “[a]n isolated or a purified protein involved in the virulence of a *Leishmania* parasite, comprising.” Claim 2 encompasses more than one protein since it is drafted with the open transitional phrase, “comprising.” Pending claims 3, 18, 19, and 22 and new Claims 36-45 simply add limitations to the subject matter of Claim 2. Applicants respectfully request that these rejections of Claims 3, 18, 19, and 22 under 35 U.S.C. § 112, second paragraph be withdrawn.

VII. Rejection under 35 U.S.C. § 101

The Examiner rejected Claims 2 and 3 under 35 U.S.C. § 101 because the claims describe a product of nature. (*Id.* at 17.) Applicants have amended Claims 2

and 3 to recite, "[a]n isolated or a purified protein." Applicants respectfully request that the rejections of Claims 2 and 3 under 35 U.S.C. § 101 be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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